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### **3 510(k) Summary Statement**

#### **General Information:**

As required by Section 12 of the Medical Devices Act of 1990, Reliant Technologies, Inc. has provided a summary of the safety and effectiveness information pertaining to the Reliant Laser System.

Submitter:	Reliant Technologies, Inc.
Address:	260 Sheridan Ave. Suite 309 Palo Alto, CA 94306
Contact Person:	Heather Tanner, Regulatory Affairs
Telephone:	(650) 473-0200 ext. 103
Facsimile:	(650) 473-0357
Date prepared:	October 25, 2003
Device Trade Name:	Reliant Laser System
Common Name:	Dermatology Laser
Classification Name:	Laser Surgical Instrument 21 C.F.R § 878.4810
Legally Marketed Predicate Devices:	Lumenis Ultrapulse Encore (K022060)

#### **Description of the Reliant Laser System:**

The Reliant Laser System consists of a set of diode lasers, controlled by an embedded processor, to be used in dermatology for the coagulation of soft tissue. The laser system uses scanning and focusing optics to deliver a pattern of thermal energy to the epidermis and upper dermis.

#### **Indications for use of Reliant Laser System:**

The Reliant Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue.

#### **Performance Standards:**

As a laser product, the Reliant Laser System complies with 21 CFR § 1010 and 21 CFR § 1040.

#### **Statement of Substantial Equivalence:**

The Reliant Laser System is substantially equivalent to the cited legally marketed predicate device for the indication listed.

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## References

1. Stuzin J, Baker, TJ, Baker, TM, Kligman AM. Histologic Effects of the High-Energy Pulsed CO<sub>2</sub> Laser on Photoaged Facial Skin *Plas & Recon Surg*.99(7): 2036-2050 (1997).
2. Fitzpatrick RE, Goldman MP, Satur NM, Tope WD. Pulsed carbon dioxide laser resurfacing of photoaged facial skin. *Arch Dermatol*. 1996;132:395-401.
3. Kirsch, Kristin M. BS. Zelickson, Brian D. MD. Zachary, Christopher B. FRCP. Tope, Whitney D. MPhil, MD. Ultrastructure of Collagen Thermally Denatured by Microsecond Domain Pulsed Carbon Dioxide Laser. *Archives of Dermatology*. 134(10):1255-1259, October 1998.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Heather Tanner  
Clinical Research  
Reliant Technologies, Inc.  
260 Sheridan Avenue, Suite 309  
Palo Alto, California 94301

Re: K031795

Trade/Device Name: Reliant Laser System  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: October 9, 2003  
Received: October 16, 2003

Dear Ms Tanner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for* *Miriam C. Provost*  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### 1.3 Indications for Use Statement

Premarket Notification [510(k)] Number: K031795

Device Name: Reliant Laser System

Indications for use: Dermatological procedures requiring the coagulation of soft tissue

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices  
510(k) Number K 031795